K122715

JUN 17 2013

510(k) Summary – Stellar 150

Date prepared	August 31, 2012
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Official contact	Jim Cassi Vice President, Quality Assurance Americas ResMed Corp. 9001 Spectrum Center Blvd., San Diego CA 92123 USA Tel: +1 858-836-6081 Fax: +1 858-836-5522
Proprietary name	Stellar 150
Common name	Continuous ventilator
Classification	21 CFR 868.5895 Product code MNT Ventilator, continuous, minimal ventilatory support, facility use
Predicate Devices	Stellar 150 (K113640) Respironics Trilogy series Remote Alarm (K111610)
Reason for submission	New Remote Alarm accessory

Intended Use

The device is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb / 13 kg and above) with respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. The device is for non-invasive use, or invasive use (with the use of the ResMed Leak Valve). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.

Device Description

The Stellar 150 is a pressure controlled ventilator using a single limb vented circuit, product code MNT, and is substantially equivalent to the already marketed Stellar 150 device (K113640). The device contains a microprocessor controlled blower that generates the required airway pressure. CPAP and Bi-level modes are implemented and the device is suitable for patients weighing above 30 lbs (13 kg) for CPAP and Bi-level modes. The device also includes a volume assured pressure support mode (iVAPS), indicated for patients above 66 lbs (30 kg).

This submission updates the Stellar 150 to include a new Remote Alarm (optional) accessory. The Remote Alarm generates an audible and visual signal when an alarm is triggered on the ventilator. For the connection of this new Remote Alarm, the Stellar 150 requires an additional connector on the back of the device as well as electronics and software support for this additional port. This new Remote Alarm triggers this 510[k].

Performance Data

The Stellar 150 remains unchanged from the predicate Stellar 150 (K113640) in terms of technology as well as in terms of the operation modes. Design and system verification testing in regards to mechanical and environmental testing according to IEC 60601-1-11:2010, electrical safety testing according to IEC 60601-1:2005, EMC testing according to IEC 60601-1-2:200, etc. was performed and shows that the device is substantially equivalent to the predicate device (K113640).

A regression analysis identified the features which were changed and which test cases needed to be repeated. End-to-end testing on the appropriate test cases has been performed. The results of the tests as well as the existing data from the K113640 submission, demonstrate that the Stellar 150 meets the predetermined acceptance criteria and is substantially equivalent to the predicate device (K113640).

The Remote Alarm was compared to the Respironics Trilogy series Remote Alarm (K111610). The result of this comparison is that the Remote Alarm is substantially equivalent to the Trilogy Remote Alarm (K111610).

The compatibility of Stellar 150 with the Remote Alarm was tested and confirmed. In addition verification testing for the Remote Alarm was performed and demonstrated that it met the predetermined acceptance criteria.

Substantial Equivalence

The Stellar 150 is substantially equivalent to the previously cleared predicate device Stellar 150 (K113640).

- Same indication for use
- Same operating principle
- Same technologies
- Similar manufacturing process

The new optional Stellar accessory, the Remote Alarm, is substantially equivalent to the Remote Alarm of the Respironics Trilogy series in terms of operating principle and technology. (K111610).

Conclusion

The indications for use, technological characteristics, and principles of operation are similar to the predicate devices. Performance data demonstrate that the new device Stellar 150 is substantially equivalent to our predicate device Stellar 150 (K113640) and the Remote Alarm is substantially equivalent to the Respironics Trilogy series Remote Alarm (K111610).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

ResMed Germany, Inc.
Mr. Jim Cassi
Vice President, Quality Assurance Americas
ResMed Corporation
9001 Spectrum Center Boulevard
SAN DIEGO CA 92123

Re: K122715
Trade/Device Name: Stellar 150
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MNT
Dated: June 4, 2013
Received: June 6, 2013

Dear Mr. Cassi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

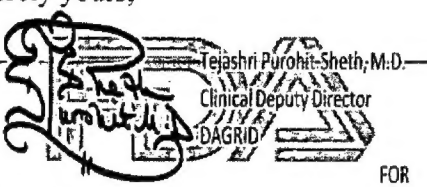
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122715

Device Name: Stellar 150

Indications for Use:

The device is intended to provide ventilation for non-dependent, spontaneously breathing adult and pediatric patients (30 lb / 13 kg and above) with respiratory insufficiency or respiratory failure, with or without obstructive sleep apnea. The device is for non-invasive use, or invasive use (with the use of the ResMed Leak Valve). Operation of the device includes both stationary, such as in hospital or home, or mobile, such as wheelchair usage.

Prescription Use ____X____ AND/OR Over-The-Counter Use____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

Anya C. Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.06.13 09:01:05 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122715